K110971

JAN 10 2012

510(k) SUMMARY

Navotek Medical Ltd. - Tracer Implantation Kit

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Navotek Medical Ltd.

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Date Prepared: March 30, 2011

Name of Device and Name/Address of Sponsor

Tracer Implantation Kit and IndeX Implantation Kit

Navotek Medical Ltd.

POB 201, 5 HaCarmel St.

Yokneam 20692, Israel

Common or Usual Name

Soft tissue fiducial marker

Classification Name

Medical linear accelerator

Regulation Number

CFR 892.5050 (Medical charged-particle radiation therapy system)

Product Code

IYE

Device Class

II

Predicate Devices

Navotek RealEye System and Calypso 4D Localization System (Tracer)

Visicoil soft tissue marker (IndeX)

Intended Use / Indications for Use

Tracer:

The Tracer Implantation Kit is indicated for use to radiographically and radioactively mark soft tissue for future therapeutic procedures.

The Tracer is indicated for permanent implantation in the prostate.

The Tracer is intended to be used in conjunction with the RealEye system as an adjunct in treatment planning and radiation therapy, to align and monitor the patient's position relative to the isocenter of a linear accelerator.

IndeX:

The IndeX Implantation Kit is indicated for use to radiographically mark soft tissue for future therapeutic procedures.

The IndeX is intended to be used as a radiographic fiducial marker for visualization using x-ray, CT, or Cone Beam CT.

Technological Characteristics

The Tracer is a Platinum/Iridium radioactive soft tissue fiducial for implantation in the prostate, in or near the treatment target for radiotherapy treatments. The Tracer emits

photons that enable its localization by the Navotek RealEye system that is designed to track localized gamma-emitting radioactive sources.

The implantation of the Tracer is performed using an Implantation Device, which is supplied with the Tracer pre-loaded within it. Therefore, the Tracer is supplied as a 'Tracer Implantation Kit' which includes the Tracer and the Implantation Device. The Tracer Implantation Kit is provided in a single package, sterile (by gamma radiation) and ready for use. It is intended for single use only.

The IndeX is identical to the Tracer in all respects except that it is not radioactive. It is intended for use to radiographically mark soft tissue and to be visible in x-ray, CT, and Cone Beam CT images.

Performance Data

Performance testing demonstrates that the Tracer and the Tracer Implantation Device perform according to specifications and function as intended. Performance testing further demonstrates that differences in technology compared to the predicate device do not impact safety or effectiveness.

Biocompatibility testing was performed according to ISO 10993- Part 1 (2003) and the FDA Blue book memorandum G95-1. Testing included platinum leakage testing with respect to platinum toxicity and radioactive leakage testing to demonstrate that the Tracer meets the requirements for a sealed source according to ISO 2919 with classification ISO/99/C53211(X). Bench, animal, and clinical testing also was conducted and demonstrated substantial equivalence to the predicate device.

All testing that is not directly related to radioactivity applies to both the Tracer and the IndeX.

Substantial Equivalence

The Tracer and its predicates have the same intended use and similar indications, and similar technological characteristics and principles of operation. The identified technological differences do not raise any new types of safety or effectiveness questions. Performance testing demonstrates that the identified technological differences between the Tracer and the predicate device do not impact safety or effectiveness. In particular, bench, animal, and clinical testing results demonstrate that the safety and performance of the Tracer are similar

to that of its predicate device. Thus, the Tracer is substantially equivalent to its predicate device.

The IndeX and its predicate have the same intended use and indications, and similar technological characteristics and principles of operation. The identified technological differences do not raise any new types of safety or effectiveness questions. Performance testing demonstrates that the identified technological differences between the IndeX and the predicate device do not impact safety or effectiveness. In particular, bench, animal, and clinical testing results demonstrate that the safety and performance of the IndeX are similar to that of its predicate device. Thus, the IndeX is substantially equivalent to its predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Navotek Medical Ltd.
% Mr. Steven B. Datlof, M.D., J.D.
Regulatory Counsel
Hogan Lovells US LLP
1835 Market Street, 29th Floor
PHILADELPHIA PA 19103

JAN 10 2012

Re: K110971
Trade/Device Name: Tracer Implantation Kit and IndeX Implantation Kit
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE, NEU
Dated: December 2, 2011
Received: December 2, 2011

Dear Mr. Datlof:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K110971

Device Name: Tracer Implantation Kit and IndeX Implantation Kit

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Prescription Use ___ √___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Mary S Pastel

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

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